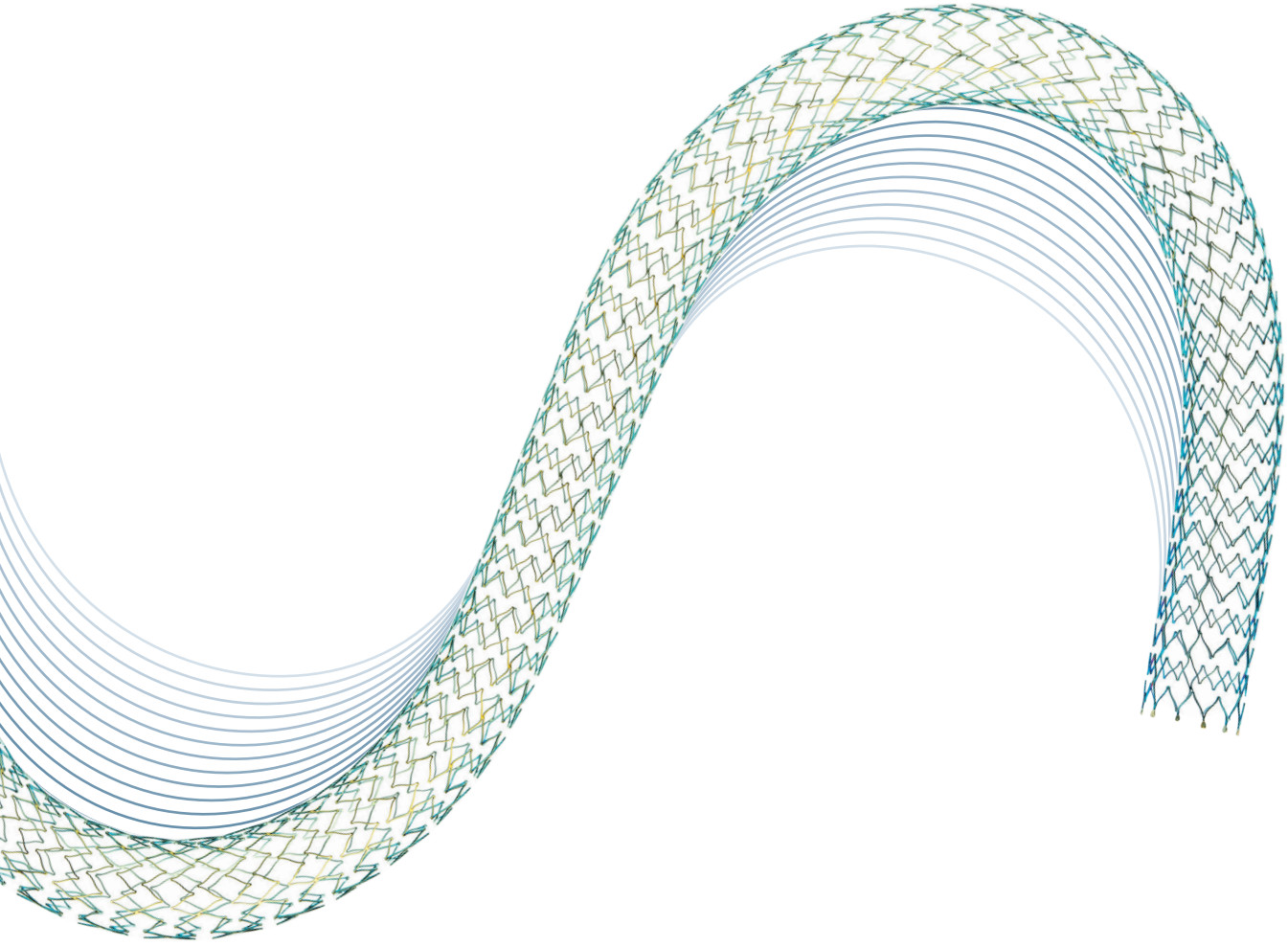
Vascular Intervention // Peripheral
Self-Expanding Stent System / 0.035" / OTW

Pulsar®-35



- 140 µm thin struts
- Clinically proven
- Tri-axial delivery system

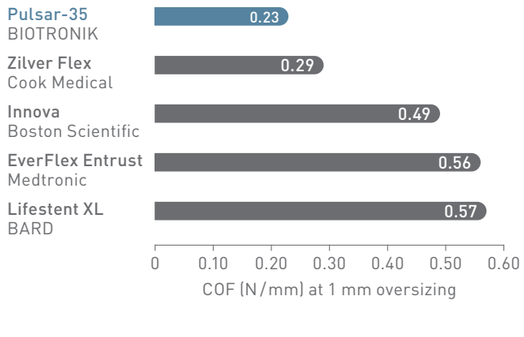
BIOTRONIK
excellence for life

Pulsar-35

Clinically proven thin struts stent with tri-axial delivery system.

140 µm thin struts - thinner than the leading brands[1]

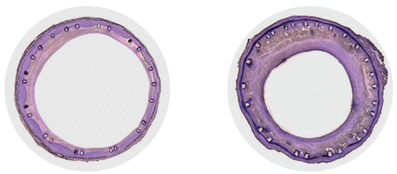
Thinner struts for low Chronic Outward Force (COF)[2]



Thinner struts and lower COF make a difference:*

- Lower risk of restenosis[3]
- Reduced vessel injury and inflammation[3]
- Faster endothelialization[4,5]

Vessel response on SE stent 1 mm oversizing showing neointimal hyperplasia at 90 days[6*]

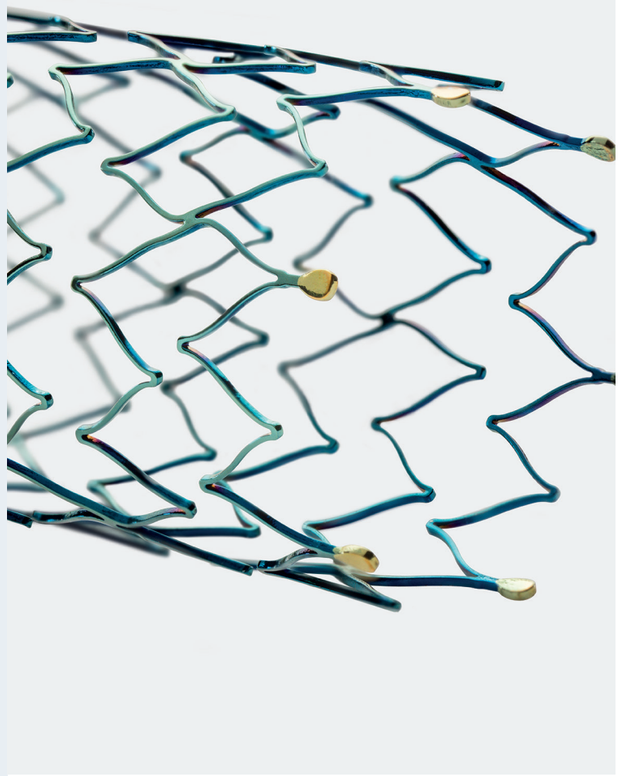


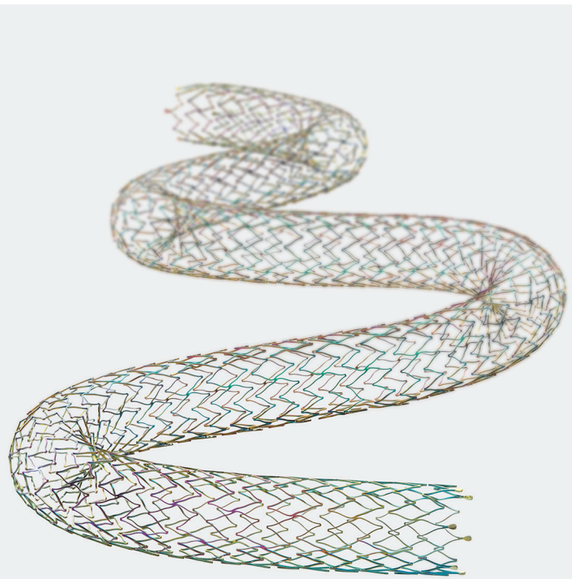
Pulsar Stent
BIOTRONIK
Low COF

Lifestent XL
BARD
High COF

*As demonstrated in pre-clinical studies

Stent strut thickness in perspective[1]





Clinically proven

Long term safety and efficacy (24-month data)

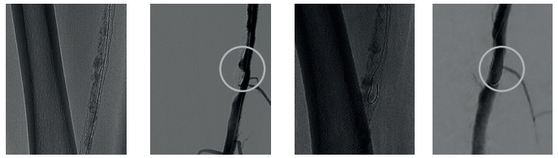
Clinically proven even in calcified lesions (4EVER), total occlusions (TASC D) and in all-comers registry (BIOFLEX PEACE).¤

	A.L.L	12 months PP	12 months FTLR	24 months PP	24 months FTLR
ALL-COMERS BIOFLEX PEACE[7] (stent only)	8.2 cm	84.7%	**89.3%**	78.4%	**89.3%**
4F INTERVENTIONS 4EVER[8]	7.1 cm	81.4%	**89.3%**	72.3%	**82.7%**
LONG & OCCLUDED TASC D[9]	24.5 cm	77.0%	**86.0%**	-	-

¤Clinical outcomes of Pulsar-18 can be used to illustrate clinical outcomes of Pulsar-35 due to identical stent platforms

89.3%
24-month FTLR
BIOFLEX PEACE

Sufficient radial force for a long term vessel support, even in calcified lesions



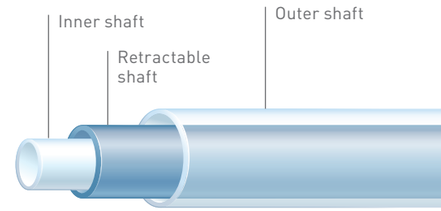
After the treatment 2011
(Courtesy of Prof. van den Berg[10])

2016

Accurate stent deployment

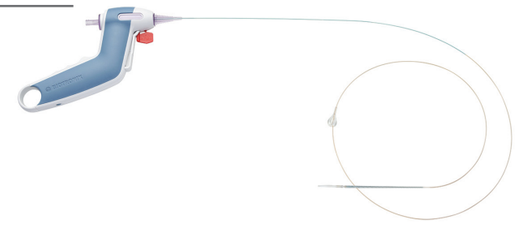
Tri-axial delivery system

The outer shaft isolates the retractable shaft from friction caused by the introducer valve to ensure accurate stent deployment.



Easy release handle

One-handed stent release handle, ergonomically designed for a comfortable and stable handling.



**FTLR - Freedom from Target Lesion Revascularization;
†PP - Primary Patency; ††A.L.L. - Average Lesion Length

Pulsar-35

Vascular
Intervention
Peripheral

Indicated for use in patients with atherosclerotic disease of the femoral and proximal popliteal arteries, in particular for the treatment of insufficient results after percutaneous transluminal angioplasty (PTA).*

Technical Data

Stent	
Catheter type	OTW
Recommended guide wire	0.035"
Stent material	Nitinol
Strut thickness	140 µm
Strut width	85 µm
Stent coating	proBIO® (Amorphous Silicon Carbide)
Stent markers	6 gold markers each end
Sizes	ø 5.0 - 7.0 mm; L: 30 - 200 mm
Proximal shaft	6F, hydrophobic coating
Usable length	90 and 135 cm

Ordering Information

	Stent ø (mm)	Catheter length 90 cm (Stent length mm)								
		30	40	60	80	100	120	150	170	200
6F	5.0	379878	379879	379880	379881	379917	379918	379919	379920	379921
	6.0	379883	379884	379885	379886	379922	379923	379924	379925	379926
	7.0	379888	379889	379890	379891	379927	379928	379929	379930	379931

	Stent ø (mm)	Catheter length 135 cm (Stent length mm)								
		30	40	60	80	100	120	150	170	200
6F	5.0	379898	379899	379900	379901	379937	379938	379939	379940	379941
	6.0	379903	379904	379905	379906	379942	379943	379944	379945	379946
	7.0	379908	379909	379910	379911	379947	379948	379949	379950	379951

1.BIOTRONIK data on file. 6.0 mm diameters; 2. BIOTRONIK data on file. 6.0 mm diameters. Supera stent not possible to test due to its design and applied test method; 3. Zhao HQ Late stent expansion and neointimal proliferation of oversized nitinol stents in peripheral arteries. Cardiovasc. Interv. Radiol. 2009; 32(4); 720-6; 4. Koskinas C. Role of endothelial shear stress in stent restenosis and thrombosis: pathophysiologic mechanisms and implications for clinical translation. JACC 2012 10;59(15):1337-49; 5. Koppara T. Thrombogenicity and early vascular healing response in metallic biodegradable polymer-based and fully bioabsorbable drug-eluting stents. Circ Cardiovasc Interv. 2015 8(6):e002427; 6. Funovics M. Correlation between chronic outward force (COF) and neointimal hyperplasia in self-expanding nitinol stents in swine in clinically relevant oversizing ranges. Presented at: LINC, Jan 26, 2017; Leipzig, Germany; 7. Lichtenberg et al. Effectiveness of the Pulsar-18 self-expanding stent with optional drug-coated balloon angioplasty in the treatment of femoropopliteal lesions - the BIOFLEX PEACE All-Comers Registry.Vasa (2019), 1-9. doi_10.10240301-1526a000785; 8.Bosiers M et al. 4-French - compatible endovascular material is safe & effective in the treatment of femoropopliteal occlusive disease: Results of the 4EVER Trial. ENDOVASC THER 2013; 20: 746-756; 9. Lichtenberg M. Superficial Femoral Artery TASC D registry: 12-month effectiveness analysis of the Pulsar-18 SE nitinol stent in patients with critical limb ischemia. J Cardiovasc Surg (Torino). 2013 ; 54(4):433-9; 10. BIOTRONIK data on file.

Leading competitors have been selected based on the PV Stent Revenue Market Shares EU, 2017 and PV Revenue Market Shares APAC 2015; (Source: Millennium Research Group Inc.). Latest SFA self expanding stents for each manufacturer; Zilver and Zilver Flex are trademarks or registered trademarks of Cook Medical Technologies or its affiliates. Innova is a trademark or registered trademark of Boston Scientific or its affiliates. Everflex and Entrust are trademarks or registered trademarks of Medtronic or its affiliates. Lifestent is a trademark or registered trademark of C. R. Bard or its affiliates. Supera is a trademark or registered trademark of the Abbott Group of Companies. S.M.A.R.T. Control is a trademark or registered trademark of Cardinal Health or its affiliates.

*Indication as per IFU.

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